Reference number(s)
2174-A

SPECIALTY GUIDELINE MANAGEMENT

SYNRIBO (omacetaxine mepesuccinate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication[1]
Treatment of adult patients with chronic or accelerated phase chronic myeloid leukemia (CML) with resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKIs)

B. Compendial Use[2-3]
1. Treatment of patients with advanced phase CML (accelerated phase)
2. Follow-up therapy for CML patients after hematopoietic stem cell transplant (HSCT)
3. Treatment of chronic phase CML in patients with a T315I mutation or disease that is resistant or intolerant to two or more tyrosine kinase inhibitors (TKIs)

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Chronic myeloid leukemia (CML), chronic phase[1,2]
Authorization of 12 months may be granted for the treatment of chronic phase CML when members have a T315I mutation or have experienced resistance, toxicity, or intolerance to prior therapy with two or more TKIs (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib)

B. Chronic myelogenous leukemia, accelerated phase (AP-CML)[1-3]
Authorization of 12 months may be granted for the treatment of accelerated phase CML when diagnosis was confirmed by detection of the BCR-ABL gene by cytogenetic and/or molecular testing.

C. CML, post-hematopoietic stem cell transplant (HSCT)[2-3]
Authorization of 12 months may be granted for members who have received a HSCT for CML when the diagnosis of CML was confirmed by detection of the BCR-ABL gene by cytogenetic and/or molecular testing.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

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IV. REFERENCES

1. Synribo [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; June 2017.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 28, 2018.
3. The NCCN Clinical Practice Guidelines in Oncology® Chronic Myelogenous Leukemia (Version 4.2018). © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 28, 2018.